

### **REMARKS**

In the present communication, claims 1, 7, 9, 12 and 13 have been amended; claims 4 and 10 have been canceled without prejudice or disclaimer; and no new claims have been added. The amendments add no new matter and are fully supported by the specification and claims as filed as discussed below. Upon entry of the present amendment, claims 1, 3, 5-9, 11-14 and 27-29 will be pending in this application.

### **Claim Amendments and New Claims**

Claims 1, 7, 9, 12 and 13 have been amended to clarify the invention. As amended, claims 1 and 9 recite the limitations of canceled claims 4 and 10 that sorcin expression is increased. The claims have been further amended to clarify that sorcin expression and contractile function are increased as compared to sorcin expression and contractile function prior to administration. Support for the amendments may be found throughout the specification and claims as originally filed, for example, in paragraphs [0006], [0018], [0020], [0047]-[0049] and [0052] of the application as published (U.S. Patent Application Publication No. 2007/0041942). As such, no new matter is introduced by the amendments which are fully supported by the specification and claims as filed.

### **Oath/Declaration**

The Office Action alleges that the originally submitted oath or declaration is defective since the oath or declaration fails to identify the application by number and filing date as well as including non-initialed or non-dated alterations. Applicants submit herewith a new declaration rendering the rejection moot.

### **Rejections under 35 U.S.C §112, first paragraph (enablement)**

Applicants respectfully traverse the rejection of claims 1, 3-14 and 27-29 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement.

In determining whether the enablement requirement has been met, an analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether the disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. *See*, M.P.E.P. §2164.01 . Applicants assert that the enablement requirement is met, since one skilled in the art could clearly make and use the claimed invention based on the application as filed as well as the level of knowledge of one skilled in the art.

Without acquiescing to the rationale presented in the Office Action, claim 11 has been amended to recite that administration of the viral vector encoding sorcin results in increased sorcin expression and contractile function as compared to sorcin expression and contractile function prior to administration. As acknowledged in the Office Action, the application exemplifies delivery of viral vectors encoding sorcin to heart tissue resulting in increased expression of sorcin. However, the Office Action contends that Seidler et al. (*Circ Res.*, 93:132-139 (2003)) show that increased expression of sorcin in cardiac tissue may not be sufficient or even adequate to achieve the claimed function of increasing heart contractility since the reference shows that adenoviral delivered sorcin actually reduced fractional shortening of cardiac muscle cells *in vitro*.

As acknowledged by the Examiner, Seidler et al. provide *in vitro* data as opposed to *in vivo* data as provided in the instant application. Regardless of this distinction, Applicants submit herewith a declaration under 37 C.F.R. §1.132 by Dr. Wolfgang Dillmann, a co-inventor of the claimed subject matter. Exhibit A of the declaration includes additional data from *in vivo* experiments showing that delivery of adeno-associated virus expressing sorcin (AAV-sorcin) to cardiac muscle in the hearts of mice improved cardiomyocyte contractility. Specifically, the data shows that increased sorcin expression improves cardiomyocyte contractility in hearts with heart failure.

Also included as an exhibit to the declaration is Exhibit B (Frank et al., *Journal of Molecular and Cellular Cardiology*, 38:607-615 (2005)). Exhibit B is a 2005 publication showing both *in vivo* and *in vitro* data of increased cardiac contractility resulting from increased expression of adeno-viral delivered sorcin. Specifically, Exhibit B shows *in vitro* transfection of

healthy adult rat cardiomyocytes transfected with adenovirus encoding sorcin, resulting in increased expression of sorcin and improved cardiac contractility (see Exhibit B, entire document). Similarly, Exhibit B shows *in vivo* delivery by direct injection into healthy adult rat heart of adenovirus encoding sorcin, resulting in increased expression of sorcin and improved cardiac contractility (see Exhibit B, entire document).

As discussed by Dr. Dillmann, the results presented in Exhibits A and B indicate that increased expression of sorcin improves cardiac contractility in cardiomyocytes and therefore presents a viable option for treatment and prevention of diseases which exhibit decreased cardiac output, such as heart failure. Contrary to the assertions of the Office Action one skilled in the art would not be required to engage in undue trial and error experimentation in order to practice the invention. As acknowledged in the Office Action, the application includes ample teachings and data showing increased expression of sorcin in cardiomyocytes resulting in increased cardiac contractility. Additionally, Exhibits A and B to the declaration show experimental results including increased expression of sorcin in cardiomyocytes resulting in increased cardiac contractility. Based on the foregoing, it is therefore reasonable to conclude that one of skill in the art would have expected similar results as those discussed showing increased cardiac contractility in cardiomyocytes transfected with a sorcin encoded viral vector *in vivo*. Such a task could be performed without undue experimentation given the level of knowledge of one skilled in art at the time of filing coupled with the application as supported by data presented in Exhibits A and B of the declaration.

In view of the foregoing, Applicants assert that the claims are fully enabled since one skilled in the art would be able to make and use the claimed invention without undue experimentation. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

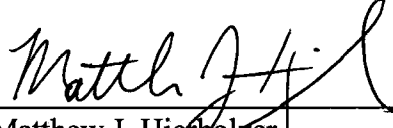
**CONCLUSION**

Applicants believe that the present application is now in condition for allowance. Favorable consideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge \$65.00 as payment for the Petition for One-Month Extension of Time fee to Deposit Account No. 07-1896. Additionally, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-referenced Attorney docket number.

Respectfully submitted,

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Matthew J. Hieholzer  
Registration No. 53,021  
Telephone: (858) 638-6638  
Facsimile: (858) 677-1465

DLA Piper LLP (US)  
4365 Executive Drive, Suite 1100  
San Diego, California 92121-2133  
**USPTO Customer Number 28213**